

K 90640 MAR 2 0 2001

Special 510(k): Device Modification
SIEMENS INFINITY Medical Information Bus (MIB II) Protocol Converter

510(k) SUMMARY

as required per 807.92(c)

Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: Connie Hertel, Director, QA/RA
Contact person for this submission: Penelope H. Greco
Date submission was prepared: March 1, 2001

Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens Medical Information Bus (MIB II) Protocol Converter

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Product Code	Class	Regulation Number
Transducer Signal amplifier and conditioner	DRQ	II	21 CFR 870.2060

Legally Marketed Device Identification:

Siemens Medical Information Bus (MIB) Protocol Converter:
510(k) K970368, K973222, K991661, K003248

Description of Modification:

The Medical Information Bus (MIB) Protocol Converter has received four 510(k) clearances.

1. 510(k) K970368 was cleared for interface with Siemens SV300 ventilator and the Baxter Vigilance blood gas/continuous cardiac output monitor.
2. 510(k) K973222 was cleared for interface with Puritan Bennett 7200 ventilator, the Draeger Evita II, Draeger Evita IV, and Draeger Babylog ventilators, and Siemens SV900 ventilator.
3. 510(k) K991661 was cleared for interface with
Anesthesia Systems
Dräger Narkomed II Dräger Narkomed IV Dräger Julian Ohmeda 7900
Point of Care Blood Gas Analyzers
Abbott Oximetrix 3
AVL Medical Instruments
Opti Critical Care Analyzer, Portable Blood Gas Analyzer
Optical Sensors Inc.
OSI – Optical CAM
VIA Medical
VIA V-ABG1 Blood Gas Chemistry Monitor
4. 510(k) K003248 was cleared for interface with the Aspect BIS monitor

COMPANY CONFIDENTIAL

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SIEMENS INFINITY Medical Information Bus (MIB II) Protocol Converter

The new MIB II protocol converter employs the same fundamental scientific technology and has the same intended use as that of the predicate device. The MIB II supports the same devices and device specific cables as that of the predicate device [510(k) K970368, K973222, K991661 and K003248]. Modifications have been implemented to support the new IEEE 1073.3.2-2000, Standard for Medical Communications – Transport Profile – IrDA Based – Cable Connected.

Although the physical connection, electrical interface, and the software protocol have been modified, the end-to-end functionality remains the same as the original MIB protocol converter implemented using the IEEE 1073.3.1 standard. Testing has been performed to validate the overall performance of the modified MIB protocol converter and to verify proper communication with the INFINITY modular bedside monitors and the MIB supported devices.

Electromagnetic compatibility testing has been performed by Chomerics Test Services in accordance with EN 60601-1-2, Part 2, Medical Electrical Equipment Collateral Standard: Electromagnetic compatibility, and in accordance with FDA suggestions.

Intended Use:

The Siemens Medical Information Bus (MIB) Protocol Converter is intended for use in an environment where patient care is provided by healthcare professionals (Physician, Nurse, Technician) when the professional determines that a third party medical device should be connected to Siemens INFINITY Modular Monitors (SC 7000 / SC 9000 / SC 9000XL) for display of data from devices such as:

- Siemens SV 300 ventilator
- Baxter Vigilance blood gas/continuous cardiac output monitor
- Siemens SV900 ventilator
- Draeger Evita II ventilator
- Draeger Evita IV ventilator
- Draeger Babylog ventilator
- Puritan Bennett 7200 ventilator
- Draeger Narkomed II Anesthesia System
- Draeger Narkomed IV Anesthesia System
- Draeger Julian Anesthesia Machine
- Ohmeda 7900 Anesthesia Machine
- Abbott Oximetrix 3 Blood Gas Analyzer
- AVL Medical Instruments: Opti Critical Care Analyzer Portable Blood Gas Analyzer
- Optical Sensors Inc.: OSI – Optical CAM
- VIA Medical: VIA V-ABG1 Blood Gas Chemistry Monitor
- Aspect A-2000 BIS Monitor*

*The SC 9000 does not support communication with the Aspect BIS Monitor

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Assessment of non-clinical performance data for equivalence: Section J

Assessment of clinical performance data for equivalence: Not applicable

Biocompatibility: Not applicable

Sterilization: Not applicable

Standards and Guidances: 1073.3.2 – 2000 IEEE Standard for Medical Communications
Transport Profile – IrDA Based – Cable Connected

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MAR 20 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Penelope H. Greco
Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923

Re: K010640
Trade Name: Siemens Medical Information Bus (MIB II)
Protocol Converter
Regulatory Class: II (two)
Product Code: DRQ
Dated: March 1, 2001
Received: March 5, 2001

Dear Ms. Greco:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

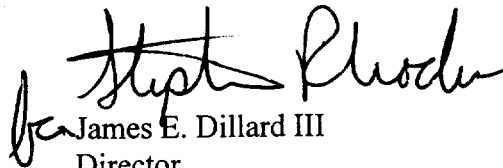
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III", is written over the typed name.

James E. Dillard III
Director

Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indicated Use Statement

Page 1 of 1

510(k) Number (if known): K010640

Device Name: Siemens Medical Information Bus (MIB II) Protocol Converter

Indications for Use:

The Medical Information Bus (MIB) Protocol Converter is indicated for use in an environment where patient care is provided by healthcare professionals (Physician, Nurse, Technician) when the professional determines that third party devices that do not provide data per the IEEE 1073 Medical Information Protocol Standard should be connected to a Siemens INFINITY Modular Monitor (SC 9000 / SC 7000 / SC 8000 / SC 9000XL) for the display of data. MIB connectivity to third party medical devices such as:

Siemens SV 300 ventilator
Baxter Vigilance blood gas/continuous cardiac output monitor
Siemens SV900 ventilator
Draeger Evita II ventilator
Draeger Evita IV ventilator
Draeger Babylog ventilator
Puritan Bennett 7200 ventilator
Draeger Narkomed II Anesthesia System
Draeger Narkomed IV Anesthesia System
Draeger Julian Anesthesia Machine
Ohmeda 7900 Anesthesia Machine
Abbott Oximetrix 3 Blood Gas Analyzer
AVL Medical Instruments: Opti Critical Care Analyzer, Portable Blood Gas Analyzer
Optical Sensors Inc.: OSI - Optical CAM
VIA Medical: VIA V-ABG1 Blood Gas Chemistry Monitor
*Aspect A-2000 BIS Monitor

*The SC 9000 does not support communication with the Aspect BIS Monitor

MRI Compatibility Statement:

The Medical Information Bus (MIB II) Protocol Converter is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

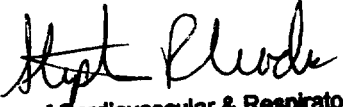
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)


Division of Cardiovascular & Respiratory Devices
510(k) Number K010640